

**COLOMBIA**

**STRENGTHENING THE EXPANDED PROGRAM ON IMMUNIZATION (EPI)  
2005-2008**

**(CO-L1002)**

**LOAN PROPOSAL**

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## ABBREVIATIONS

ARS	Administradores de Riesgos en Salud [Health Risk Managers] (insurers responsible for administering the subsidized health scheme)
AWPs	Annual work plans
DANE	Departamento Administrativo Nacional de Estadística [National Administrative Department of Statistics]
DHS	Demographic and Health Survey
DQAC	Data Quality Audit Colombia
EPI	Expanded Program on Immunization
EPS	Entidades promotoras de servicios de salud [Health Service Promotion Agencies] (private-sector health insurers)
ICRC	International Committee of the Red Cross
INS	Instituto Nacional de Salud [National Health Institute]
ISS	Instituto de Seguros Sociales [Social Security Institute]
MDGs	Millennium Development Goals
MPS	Ministry of Social Protection
PAB	Plan de Atención Básica [Basic Health Care Plan]
PAHO	Pan American Health Organization
PDL	Performance-driven loan
PND	Plan Nacional de Desarrollo [National Development Plan]
POS	Plan Obligatorio de Salud [Mandatory Health Plan]
PPMR	Project Performance Monitoring Report
SGSSS	Sistema General de Seguridad Social en Salud [General Social Security Health System]
TCU	Technical coordination unit
UNCITRAL	United Nations Commission on International Trade Law
WHO	World Health Organization

### Electronic Links and References

Basic socioeconomic data	<a href="http://www.worldbank.org/cgi-bin/sendoff.cgi?page=%2Fdata%2Fcountrydata%2Fict%2Fcol_ict.pdf">http://www.worldbank.org/cgi-bin/sendoff.cgi?page=%2Fdata%2Fcountrydata%2Fict%2Fcol_ict.pdf</a>
Active portfolio and loans approved	<a href="http://ops/Approvals/PDFs/COsp.pdf">http://ops/Approvals/PDFs/COsp.pdf</a>
Tentative lending program	<a href="http://opsgs1/ABSPRJ/tentativelending.ASP?S=CO&amp;L=SP">http://opsgs1/ABSPRJ/tentativelending.ASP?S=CO&amp;L=SP</a>
Information available in the RE3/SO3 technical files	<a href="http://opsws3.reg.iadb.org/idbdocswebservices/getDocument.aspx?DOCNUM=416473">http://opsws3.reg.iadb.org/idbdocswebservices/getDocument.aspx?DOCNUM=416473</a>

## PROJECT SUMMARY

### COLOMBIA STRENGTHENING THE EXPANDED PROGRAM ON IMMUNIZATION PERFORMANCE-DRIVEN LOAN (CO-L1002)

Financial Terms and Conditions <sup>1</sup>				
Borrower: Republic of Colombia			Amortization period:	25 years
Guarantor: Not applicable			Grace period:	5.5 years
Executing agency: Ministry of Social Protection			Disbursement period:	5 years
<b>Source</b>	<b>Amount (US\$ million)</b>	<b>%</b>	Interest rate:	Adjustable
IDB (Ordinary Capital)	107	80	Inspection and supervision fee:	0%
Local	26.7	20	Credit fee:	0.25%
Total	133.7	100	Currency:	United States dollars, drawn from the Ordinary Capital under the Single Currency Facility
Project at a glance				
<b>Project objective:</b>				
To make the Expanded Program on Immunization (EPI) more equitable by maintaining vaccination coverage at a suitable level for children up to five years of age, increasing it in low-coverage municipios, and strengthening the EPI's operational capabilities.				
<b>Special contractual conditions:</b>				
Mention is to be made in the loan contract of the condition that the Pan American Health Organization (PAHO) is to be contracted to carry out the procurement of biologicals, using its revolving fund for this purpose, prior to the first disbursement. <a href="#">See paragraph 4.10.</a>				
<b>Exceptions to Bank policies:</b>				
The borrower has requested, as an exception to Bank policy (document GN-2278-2), that in this specific case the deduction of the initial payment be spread out over the tranches of the performance-driven loan on a proportional basis. See paragraph 3.12.				
<b>Project consistent with country strategy:</b> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>				
<b>Project qualifies as:</b> SEQ <input checked="" type="checkbox"/> PTI <input checked="" type="checkbox"/> Sector <input checked="" type="checkbox"/> Geographic <input type="checkbox"/> Headcount <input type="checkbox"/>				
<b>Verified by CESI on:</b> 4 February 2005				
<b>Environmental and social review:</b> This operation will seek to improve the vaccination program's coverage, especially in the poorest municipios, whose populations include Afro-descendent and indigenous groups. In order to mitigate the risk of improper syringe disposal, a safe disposal component will be included. <a href="#">See cross-referenced paragraphs 4.4-4.6.</a>				
<b>Procurement:</b> The program will finance the purchase of biologicals, syringes, equipment, and technical assistance. Biologicals and syringes will be purchased pursuant to Law 80 of 1993, with resources drawn from the PAHO revolving fund in accordance with practices and principles of competition, economy, efficiency, and transparency. Calls for bids for the provision of technical assistance and equipment will be conducted in accordance with Bank procurement procedures. <a href="#">See cross-referenced paragraphs 1.20-1.23, 3.6-3.9, and 4.10.</a>				

<sup>1</sup> The interest rate, credit fee, and inspection and supervision fee mentioned in this document are established pursuant to document FN-568-3 Rev. and may be changed by the Board of Executive Directors, taking into account the available background information, as well as the respective Finance Department recommendations. In no case will the credit fee exceed 0.75%, or the inspection and supervision fee exceed 1% of the loan amount.\*

\* With regard to the inspection and supervision fee, in no case will the charge exceed, in a given six-month period, the amount that would result from applying 1% to the loan amount divided by the number of six-month periods included in the original disbursement period.

## I. FRAME OF REFERENCE

### A. Socioeconomic framework

- 1.1 Colombia underwent its deepest recession of the last 70 years in 1997-1999. This recession's impact on the poor was particularly severe. Recent studies on poverty trends<sup>1</sup> suggest that: (i) the crisis resulted in a considerable increase (regardless of how poverty is measured) in poverty levels in Colombia; (ii) there are signs that economic growth is improving the poverty situation in the country; (iii) poverty levels, whatever the method of measurement used, declined in 2003 in all regions, but nonetheless remain higher than pre-recession levels; (iv) there has been a bigger decrease in extreme poverty than in poverty as such; (v) rural poverty has decreased more than urban poverty has; and (vi) despite an upswing in per capita income, increased inequality has prevented poverty levels from decreasing more rapidly. This persistent inequality in income is also reflected in inequalities in access to social services, including such health care services as vaccinations.

### B. The sector

#### 1. Vaccination: A global perspective

- 1.2 Vaccination programs in developing countries warrant a high priority because of the effects that they have in terms of: (i) infant morbidity and mortality, especially in lower-income groups; (ii) a reduction in the burden represented by disease during adulthood; (iii) indirectly, the development of human capital; and (iv) a reduction in the costs of providing care for preventable diseases. In the absence of appropriate vaccination levels, vaccine-preventable diseases have a disproportionate impact on morbidity and mortality rates in the poorest quintile of the income distribution structure.<sup>2</sup> Vaccination also has a significant impact in preventing other health problems that appear long after a person has suffered from a given disease. Exposure to certain types of vaccine-preventable infectious diseases during childhood can cause permanent biological damage that may have chronic adverse effects during adulthood. There are also indirect effects, such as the negative impact on human capital produced by an illness-related reduction in hours of school attendance. National vaccination programs play an important role in eradicating transmissible diseases; examples include the programs coordinated by the Pan American Health Organization (PAHO) in an effort to eradicate polio, measles, and rubella in Latin American countries.<sup>3</sup>

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<sup>1</sup> See, for example, Vélez, Carlos Eduardo (2002), *Colombia Poverty Report*, and Santa María, Mauricio (2004), "Colombia Poverty Calculations".

<sup>2</sup> Gwatkin (2000).

<sup>3</sup> The eradication of transmissible diseases is regarded as a public good because it meets nonrivalrous consumption and nonexcludability criteria. It is highly unlikely that market mechanisms can be used to finance eradication campaigns, and such initiatives thus require public-sector support and coordination.

- 1.3 The Expanded Program on Immunization (EPI), which was launched at the global level in the 1970s, focuses on six transmissible childhood diseases (tuberculosis, poliomyelitis, diphtheria, pertussis, neonatal tetanus, and measles). It has succeeded in reducing the total burden of disease among children under five years of age from 23% of the total in the 1970s to less than 10% by 2000. The cost of vaccinating a child against these six diseases is approximately US\$17, which makes the EPI one of the most affordable and cost-effective programs in the health sector.<sup>4 5</sup>

## **2. Infant mortality and vaccine-preventable diseases in Colombia**

- 1.4 The infant mortality rate is an indicator of a country's overall economic and social development; it is also one of the Millennium Development Goal indicators. Although Colombia has witnessed a decrease in its infant mortality rate in absolute terms (from 73 deaths per 1,000 live births in 1970 to 30.6 in 2000),<sup>6</sup> the decline is regarded as a relatively modest one when compared to the progress made by other Latin American countries. Much of this decrease is accounted for by the introduction of vaccinations.
- 1.5 Although it is difficult to determine the counterfactual for a vaccination program given existing shortcomings with respect to the information available on vaccine-preventable diseases prior to the program's introduction, an examination of the causes of death in children between 0 and 1 year of age in 1972 indicates that nearly 40% of those deaths may have been related to a vaccine-preventable disease. In 2001, the percentage of deaths among children between 1 and 5 months of age (the group in which infant mortality is concentrated) caused by vaccine-preventable diseases was only 1.1% (DANE, 2001). Owing to incorrect diagnoses and misclassification of the resulting deaths, however, it is thought that these figures may underestimate the percentage of vaccine-preventable diseases.<sup>7</sup> The actual percentage of such deaths is estimated at 7.4% of the total.

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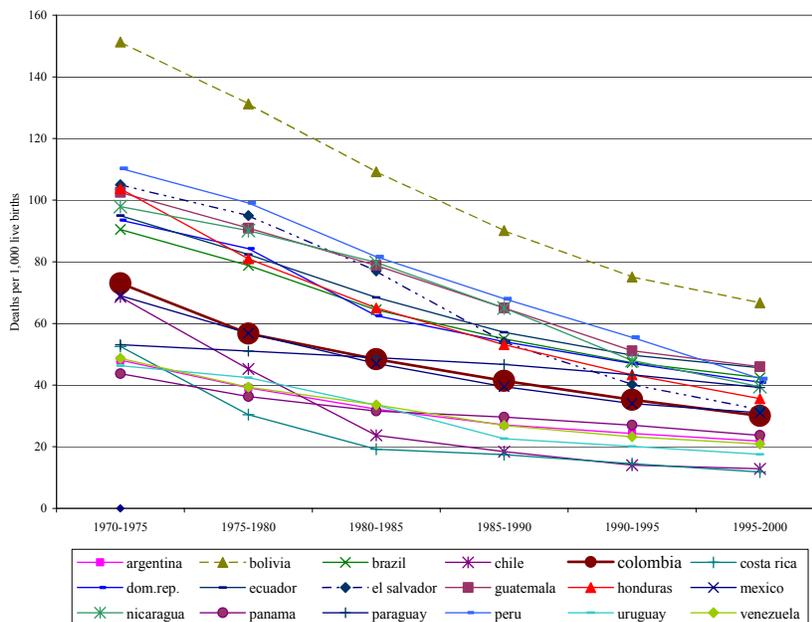
<sup>4</sup> If vaccination is to be an effective tool for eradicating disease, vaccination levels need to be maintained at between 80% and 92%, depending on the disease (Fine 1993).

<sup>5</sup> For a brief overview of the international literature on the cost-effectiveness of vaccination, see Levine, Ruth E., *Part B: Cost Effectiveness of Immunization: Asking the Right Questions*, in *The Vaccine Book*, Barry R. Bloom and Paul-Henri Lambert, eds., Academic Press, 2003.

<sup>6</sup> Demographic and Health Survey (DHS) (2000), Urdinola (2003).

<sup>7</sup> This may be the case when different diseases have similar symptoms (e.g., *Haemophilus influenzae* and pneumonia).

**Figure I-1: Trends in Infant Mortality Rates, 1970-2000**



### 3. Vaccination rates in Colombia

- 1.6 Official figures obtained from EPI administrative databases indicate that immunization coverage amounted to 15% in 1978; following the program’s introduction, coverage began to climb, reaching over 93% by 1996 for all biologicals. Coverage rates began to decline in 1997, falling to 75% and 88%, which opened the way for outbreaks of EPI diseases, such as measles, pertussis, and pneumonia. Since 2001, national coverage rates for some vaccines (DTP, polio, three-in-one viral<sup>8</sup>) have been trending upward once again and are reaching levels close to those registered in 1996 (over 90% for all biologicals).<sup>9</sup>
- 1.7 Another major problem in attaining increased coverage is that sharp geographical and demographic inequities in vaccination levels continue to exist. Vaccination coverage in the poorer, more remote municipios is far below national or departmental averages. For example, even though they have a similar number of children between 0 and 1 year of age, the Department of Tolima reports coverage rates of close to 100%, whereas the Department of Cauca exhibits levels averaging between 63% and 71%. In addition, as shown in Table I-1, children born to less educated mothers tend to have lower vaccination rates; this points to a strong correlation between poverty and a lack of access to health care services.

<sup>8</sup> The “three-in-one antiviral vaccine” refers to a vaccine against measles, mumps, and rubella (MMR).

<sup>9</sup> Using a projected denominator based on the recorded number of live births, adjusted for infant mortality and under-reporting.

**Table I-1: Vaccination Rates of Children between the Ages of 12 and 23 Months, by Mother's Level of Education, 2000 (ENDS 2000)**

PERCENTAGE OF CHILDREN BETWEEN 12 AND 23 MONTHS OF AGE WHO HAVE RECEIVED EACH VACCINATION AT ANY GIVEN POINT IN TIME											
Mother's level of education	BCG	DPT 1	DPT 2	DPT 3	Polio at birth	Polio 1	Polio 2	Polio 3	Measles	All	None
No schooling	77.6	84.3	70.5	50.6	58.3	82.0	74.8	48.3	44.4	26.7	5.5
Primary	91.1	95.2	86.6	73.4	58.6	96.8	87.3	67.6	67.6	46.9	0.8
Secondary	95.6	95.0	90.0	77.9	68.9	97.5	89.6	73.8	73.0	55.5	0.7
University	96.6	100.0	98.5	92.7	81.3	100.0	97.8	81.2	80.3	62.1	0.0
Total	93.4	95.3	88.9	76.8	65.8	97.0	89.1	71.3	70.8	52.0	0.8

- 1.8 In addition, few children are fully vaccinated at the appropriate age. The timing of vaccinations is of key importance, as the age-related vaccination calendar is based on the ability to stimulate an immunological response and the age associated with the greatest vulnerability to morbidity or to a particular disease. Furthermore, a vaccination rate below the necessary threshold value (~85%) can lead to outbreaks of the disease in question. The results of a representative nationwide survey indicate that only 52% of all children were fully vaccinated at the appropriate age in 2000. Uninsured children run a greater risk of not having been kept on an age-appropriate vaccination schedule.
- 1.9 Official vaccination rates are computed at the municipal level. Departments consolidate the municipal information and are responsible for sending these records on to the Instituto Nacional de Salud [National Health Institute] (INS), which then aggregates the information and calculates the national coverage rate. Of the country's 32 departments, 18 use data entry software that expedites the inputting of information and the calculation of coverage rates for each type of vaccine. The remaining departments experience problems with delays in submission of the information, under-reporting by municipios (some report on time, others do not), and accuracy (under- or over-reporting of vaccinations).<sup>10</sup> The size of the margin of error has yet to be determined, although a study was done on this question based on a small sample of municipios and departments in a data quality audit conducted as part of the preparations for the program.<sup>11</sup>
- 1.10 Problems have also been encountered in estimating the denominator. Colombia's most recent census was conducted in 1993, and the denominators used to calculate the EPI's current coverage rates are derived from projections (base year: 1993) prepared by the Departamento Administrativo Nacional de Estadística [National Administrative Department of Statistics] (DANE). The methods used to arrive at

<sup>10</sup> For example, coverage rates for the DPT and Hepatitis B vaccines ought to be identical, since they are administered together in a single injection (known as a "pentavalent" vaccine); in some municipios, however, the reported rates are not the same.

<sup>11</sup> Data Quality Audit Colombia (DQAC), January 2005, see: <http://opsws3.reg.iadb.org/idbdocswebservices/getDocument.aspx?DOCNUM=467245>.

these projections are more accurate at the national level, less so at the departmental level, and have a large margin of error at the municipal level owing to the country's changing demographics. The pattern of population shifts, together with the scarcity of data on internal and international migration, increasing urbanization, declining fertility rates, and the ageing of the population, make it difficult to arrive at a sound population projection at the municipal level. These unadjusted denominators are used because they are the ones employed in the legislation establishing the levels of transfers to be made to subnational levels and, hence, in determining the amount of funds to be received by subnational agencies for the EPI's implementation. After having introduced a number of reforms to standardize and centralize the country's system of vital statistics in the 1990s, since 1998, DANE has maintained a national registry of live births, which is considered to be adequate. These records can be used as an alternative to census data in estimating a national denominator for children under one year of age. After adjusting for the under-reporting of live births (17.5% of the total) and for infant mortality, this number can be estimated for the years from 2001 to 2008 in order to calculate a more suitable denominator. Nevertheless, because of the above-mentioned legal constraints, these figures cannot be regarded as official vaccination statistics for the country, even though they are of a higher quality and reflect the existing situation more accurately.

- 1.11 In order to address this situation at the municipal level, in 2002 the EPI attempted to check the information contained in administrative reports by conducting special-purpose surveys in health care facilities located in 228 different municipios. Given the design of the sample and survey, however, it has not been possible to compare the rate based on administrative records with the rate derived from the survey findings.<sup>12</sup> The EPI does, however, acknowledge the importance of conducting this type of monitoring, particularly until such time as another census is carried out.
- 1.12 Since 2001, Colombia has had an epidemiological surveillance system in place for detecting outbreaks of vaccine-preventable diseases. This system has functioned efficiently, but independently of the civil registry system. The surveillance system provides weekly reports on the number and evolution of existing cases of measles, acute flaccid paralysis, neonatal tetanus, diphtheria, pertussis, yellow fever, hepatitis B and *Haemophilus meningitis*. As part of this system, active household and institutional inspections are conducted to investigate suspicious cases; the methodologies used for such inspections are in line with international standards. In 2003, an assessment undertaken by PAHO and the government found that 89% of all health units reported suspicious cases promptly and that 80% used proper

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<sup>12</sup> The survey's shortcomings included the following: (i) the questionnaire was not sufficiently coded to ensure a reliable result; (ii) respondents were not asked for the dates on which each vaccine was administered, and it was therefore impossible to determine whether or not the vaccinations were in line with an age-appropriate schedule; (iii) the selection of municipios was based on considerations of convenience; and (iv) three different sampling methodologies were used, thereby making it impossible to compare the results with the baseline obtained from administrative data or to make sure that the sample of children between the ages of 0 and 1 year was representative.

follow-up procedures (within 4 days). The number of cases reported under this system is quite small (10 or fewer cases per year), with the exception of pertussis, pneumonia,<sup>13</sup> and hepatitis B, but it has nonetheless made it possible to establish the epidemiology of recent imported outbreaks of yellow fever (January 2004) and measles (May 2002), and to take steps to keep them from spreading to uninfected, unvaccinated members of the population. The disadvantage of this system is that it does not include any denominators that could be used to determine the percentage of morbidity or mortality attributable to these cases as compared to other sources, or the proportion of the population that has been affected. What is more, as mentioned earlier, not all the country's health units participate in it.

#### **4. The Expanded Program on Immunization (EPI) in Colombia and its institutional structure**

- 1.13 The Ministry of Health set up the EPI in Colombia in 1978 in order to provide all children between 0 and 5 years of age and other target groups with an ongoing vaccination program to protect them against what were originally six diseases. The program now also includes hepatitis B, rubella, mumps, influenza, and yellow fever.
- 1.14 In 2005, a vaccination program for the various strains of influenza will be introduced. This program will initially target the most vulnerable groups in the population: children between 6 months and 2 years of age, selected immunocompromised individuals, and health care workers.<sup>14</sup> This annual vaccine provides protection against the influenza strains identified during the preceding year's flu season but cannot prevent an epidemic caused by an unknown and/or more virulent strain. In the event of an epidemic or pandemic of this sort, Colombia has a contingency plan that is based on the recommendations made by the World Health Organization (WHO).
- 1.15 The EPI's operations are governed by the Social Security Reform Act (Law 100 of 1993) and involve political and administrative authorities at the national and subnational levels, as well as both public and private insurers and providers. The Ministry of Social Protection (MPS) defines the national immunization policy and standards and is responsible for managing and appropriating program resources. As the policy-making body for this sector, it establishes guidelines for the Plan de Atención Básica [Basic Health Care Plan] (PAB), which includes vaccinations, for the transfer of funds and functions to the municipios. It is also in charge of monitoring, follow-up, and oversight of subnational bodies and agencies in the health sector. Law 715 of 2000 was enacted in order to achieve greater transparency

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<sup>13</sup> The disease continues to be the primary cause for consultations with health practitioners for children under 5 years of age.

<sup>14</sup> During the first year that this proposed program is in operation, the cost-effectiveness of implementing a broader flu vaccination strategy in subsequent years will be analyzed.

and accountability in the levels of government involved in managing the PAB and the EPI, in particular.

**Table I-2: Age-Related Vaccination Schedule in Colombia, 2004**

AGE	VACCINATIONS	DOSE	PREVENTABLE DISEASES
<b>Newborns</b>	Tuberculosis (BCG)	Single dose	Tuberculous meningitis
	Hepatitis B (HB)	Additional dose required	Hepatitis B
	Poliomyelitis (OVP)	Additional dose	Poliomyelitis
<b>Beginning at 2 months</b>	Diphtheria – Pertussis – Tetanus (DPT)	First dose	Diphtheria, pertussis, tetanus
	Haemophilus influenzae type b	First dose	Meningitis and others caused by Haemophilus influenzae type b
	Hepatitis B (HB)	First dose	Hepatitis B
	Poliomyelitis (OVP)	First dose	Poliomyelitis
<b>Beginning at 4 months</b>	Diphtheria – Pertussis - Tetanus (DPT)	Second dose	Diphtheria, pertussis, tetanus
	Haemophilus influenzae type b	Second dose	Meningitis and others caused by Haemophilus influenzae type b
	Hepatitis B (HB)	Second dose	Hepatitis B
	Poliomyelitis (OVP)	Second dose	Poliomyelitis
<b>Beginning at 6 months</b>	Diphtheria – Pertussis - Tetanus (DPT)	Third dose	Diphtheria, pertussis, tetanus
	Haemophilus influenzae type b	Third dose	Haemophilus influenzae type b
	Hepatitis B (HB)	Third dose	Hepatitis B
	Poliomyelitis (OVP)	Third dose	Poliomyelitis
<b>At 1 year</b>	MMR (three-in-one)	First dose	Measles, mumps, rubella
	YF	First dose	Yellow fever

**BOOSTER SHOTS**

AGE	VACCINATIONS	DOSE	PREVENTABLE DISEASES
<b>1 year after third dose</b>	DPT (three-in-one bacterial vaccine)	First booster	Diphtheria, pertussis, tetanus
	Poliomyelitis (OVP)	First booster	Poliomyelitis
<b>At 5 years</b>	DPT (three-in-one bacterial vaccine)	Second booster	Diphtheria, pertussis, tetanus
	Poliomyelitis (OVP)	Second booster	Poliomyelitis
	MMR (three-in-one viral vaccine)	Booster	Measles, mumps, rubella

- 1.16 The MPS is in charge of running the program and is responsible for programming, prioritizing, monitoring, oversight, and developing management tools, as well as for the distribution of biologicals and the maintenance of a nationwide cold chain for vaccines. The Instituto Nacional de Salud [National Health System] (INS) is responsible for epidemiological surveillance and the public health laboratory. The EPI and the Superintendencia de Salud [Office of the Superintendent for Health Services] are responsible for overseeing the program's outputs.
- 1.17 Under the terms of Law 100, subnational units are responsible for health service delivery, either through the Plan Obligatorio de Salud [Mandatory Health Plan] (POS), for persons with health care coverage, or the PAB, for the uninsured.<sup>15</sup> Districts, decentralized municipios, and departments (in the case of municipios that have not yet been decentralized) are in charge of ensuring the availability of vaccination services and of arranging for, supervising, and promoting the delivery of those services. Their responsibilities in this connection include coordination with Entidades Promotoras de Salud [private-sector health insurers] (EPSs) and Administradores de Riesgos en Salud [health insurers that administer the subsidized health system] (ARS). At the subnational level, management of these services involves the departmental, district, and local health bureaus and health facilities. These units are responsible for adopting and implementing the EPI's national guidelines for each jurisdiction and for maintaining an administrative, technical, and management structure that will ensure the program's implementation at each level; this area of responsibility encompasses technical assistance, public health surveillance, quality control, advocacy, dissemination, monitoring, the production of information, and the storage and distribution of biologicals.

**a. Policy and management framework**

- 1.18 The reform program's strengths notwithstanding, both its implementation and the decentralization process itself have suffered from voids and/or duplications in the definition of the various agencies' spheres of responsibility, and this has worked to the detriment of service delivery and coverage. Organizational shortcomings have been observed in connection with: (i) enforcement of rules and policies; (ii) management, oversight, coordination, and monitoring; (iii) human resources and training; and (iv) coordination of the public and private sectors.
- **Policy framework.** The situation is unclear with respect to the enforcement of the laws governing the management and delivery of immunization services and the surveillance of vaccine-preventable diseases. The use of identification cards issued by local governments, which is at variance with national regulations, also makes it difficult to verify children's vaccination status and creates problems for the overall information system.

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<sup>15</sup> Vaccination services are included in both programs, on an individual basis in the POS and as part of collective vaccination and surveillance schemes in the PAB.

- **Management, oversight, coordination, supervision, and monitoring.** Shortcomings exist in relation to: (i) supervision, monitoring, and oversight of the program's implementation, both within the sector (national, departmental, and municipal levels), and in terms of coordination with other sectors; (ii) the allocation and timely delivery of program resources and of those provided by other sources (POS and PAB), as well as administrative delays in the conclusion of organizational arrangements; and (iii) the availability of sufficient communications and computer resources to permit proper oversight and monitoring of program activities.
- **Human resources and training.** Weaknesses exist in relation to the definition of minimum qualifications for posts, shortages of qualified technical and operational personnel, work overloads, unstable employment relationships with unqualified personnel, and a lack of motivation and uncertainty on the part of the staff. There is also a specific need for human resource training in the management and maintenance of the cold chain; more generally, the technical assistance provided by departmental agencies to the municipios needs to be strengthened.
- **Coordination of the public and private sectors.** Although there has been some success with coordination between insurers and the public sector in providing vaccinations regardless of the recipients' type of insurance coverage, the responsibility to provide immunization is chiefly shouldered by the public sector. The role of the private sector therefore needs to be clarified, and systems for coordination and cooperation between the two sectors should be strengthened. There are also some issues relating to the division of responsibilities within the sector that interfere with vaccination efforts (e.g. the requirement that insurers in the contributory and subsidized systems must purchase the syringes needed for the administration of biologicals).

1.19 In response to these challenges, which have been documented as part of the preparations made for this program, the MPS has made the necessary policy decisions to permit the efficient implementation of the proposed program. For example, the government decided to introduce a national identification card, to be printed and distributed by the central government, in order to foster the use of such cards by mothers of children under 5 years of age and to help standardize the corresponding information system. In addition, a new EPI regulation has been issued under Law 715, which would permit the municipios to make use of incentives for the achievement of suitable vaccination rates.<sup>16</sup> Supervisory, training,

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<sup>16</sup> This system should be strengthened by means of random audits of the data reported by subnational agencies. Funding for such audits has been included in the program proposal. In addition, in order to eliminate the constraints on the development of subnational denominators, as described in paragraphs 1.10-1.11, the results of the latest population and housing census (expected in the second half of 2005) are awaited.

communications, and oversight functions of the program have also been expanded and strengthened. Yet another step has been to reform the division of responsibilities among the various sectors by consolidating the bidding process for suppliers of syringes at the national level as a means of making vaccinations more readily available. This bidding process has been incorporated into the present program.

**b. Purchase of vaccines**

- 1.20 The Revolving Fund for Vaccine Procurement was developed by PAHO in 1979 to assist in the purchase of vaccines, syringes, needles, and cold chain equipment for countries in Latin America and the Caribbean. PAHO does not sell vaccines to participating countries; instead, it acts on their behalf in negotiating annual contracts for the purchase of vaccines. Using a wholesale procurement system, the Fund has ensured a supply of high-quality, affordably-priced vaccines for national immunization programs; this has also made it possible to improve the planning of immunization activities. Between 1979 and 2001, the dollar value of vaccines acquired through the Fund jumped from US\$2 million to over US\$130 million.
- 1.21 The Fund operates on the basis of an annual cycle. In July of each year, the MPS and the ministries of health of all participating countries indicate the number of vaccines they will need per quarter for the following year. PAHO then consolidates the annual figures received from the ministries of health and, in September, requests bids from all the international suppliers that have prequalified with the WHO based on the demonstrated technical quality of their products. In October, the bids are opened and agreements with international suppliers are concluded for the forthcoming year. The criteria used for the selection of suppliers are based on price and on suppliers' track records in terms of prompt delivery. When possible, two suppliers for each type of vaccine are selected. PAHO averages the prices quoted by the various suppliers for each product and distributes price lists to the participating countries. Then, once each quarter, PAHO requests confirmation from the participating countries of their requirements and places quarterly orders with the suppliers in which it specifies the quantity, recipient, and shipment date. PAHO keeps track of the orders and arranges for payment of freight charges. If delivery is made to its satisfaction, PAHO sends an invoice to the country in which it has added a commission equivalent to 3% of the cost of the vaccines. The countries have 60 days in which to reimburse the Fund. If a country falls into arrears on its payments, no further orders will be made on behalf of that country until the sum it owes has been paid. It should be noted that Colombia has an excellent payment history.
- 1.22 The terms of reference for the Fund are as follows: (i) to provide the countries with a regular supply of vaccines that meet PAHO and WHO standards at affordable prices; (ii) to allow the countries to purchase the vaccines and syringes they need for their vaccination programs while avoiding any interruptions caused by a lack of

vaccines or of immediately disposable funds; (iii) to facilitate the use of local currency to pay the corresponding invoices; (iv) to consolidate contracts so that vaccines and syringes can be purchased wholesale with a view to obtaining lower prices and better delivery terms; (v) to ensure the quality of the vaccines used in national vaccination programs; and (vi) to set up procedures with suppliers for handling rush orders and deliveries on short notice.

- 1.23 At the international level, the annual cost of purchasing biologicals has been reduced by a factor of five since the revolving fund's introduction in the Latin American countries, thanks to the economies of scale associated with buying them wholesale.<sup>17</sup> The figures for Colombia are similar.

**c. Management of biologicals at the subnational level**

- 1.24 The delivery of biologicals should be governed by the plans for their use by the municipios and departments. Delays occur, however, because of improper planning, the time and procedures involved in securing approval for the use of PAB funds and their allocation to the municipios, and inconsistencies in inventory control processes at the various levels of government. In order to remedy this situation, the EPI plans to provide technical assistance and intensive training at the municipal level for the public and private sectors; it also plans to monitor this process closely in a target group of municipios chosen on the basis of their performance in the EPI.
- 1.25 A cold chain is in operation, which includes a national vaccine storage facility that is in excellent condition. An inventory of the cold chain has been conducted down to the departmental level, and equipment for that level has been acquired. The second stage of this inventory, at the sub-departmental level, remains to be conducted, however, as do the design and provision of training in the use and maintenance of the chain at the subnational level. Strengthening the cold chain is a key task because problems with the spoilage or waste of biologicals drive up program costs and jeopardize the supply of vaccines. The reasons for these problems include: (i) the practice of discarding a vial containing multiple doses after using it to vaccinate a single child; (ii) defects in the cold chain that cause vaccines to be destroyed because they have been exposed to excessive heat (especially in the case of polio and measles vaccines) or that cause adjuvant vaccines to freeze; and (iii) insufficient inventory control, as a result of which vaccines pass their expiration date. Given the increasing cost of existing vaccines, particularly pentavalent vaccines, and the higher cost of newly developed ones, it is important to reduce waste to a minimum.

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<sup>17</sup> Maceira, Daniel, et al., Analysis of International Mechanisms Supporting Immunization Programs: The Pan American Health Organization Revolving Fund, Document No.1, The Bill & Melinda Gates Children's Vaccine Program (CVP) at the Program for Appropriate Technology in Health (PATH), Abt Associates, Bethesda, Maryland, December 2000.

### **C. The country's sector strategy**

- 1.26 The Plan Nacional de Desarrollo [National Development Plan] (PND) for 2003-2006, entitled "Toward a Communitarian State" (Law 812 of 2003), guides government action in four fundamental areas: (i) providing security within a democratic framework; (ii) promoting sustainable economic growth and job creation; (iii) building social equity; and (iv) increasing the transparency and efficiency of the State.
- 1.27 As part of the objective of building social equity, the PND states that health sector policy should seek to expand and improve social security and protection. One of the high-priority actions under this policy is the achievement and maintenance of useful vaccination coverage rates (above 95% among children under five years of age) for all of the EPI biologicals.<sup>18</sup> To attain this goal, the PND calls for the following measures: (i) issuance of a regulation making the achievement of vaccination targets mandatory; (ii) steps to lock in the necessary national budgetary resources for the purchase of biologicals for use in each of the relevant periods; (iii) definitive introduction of the pentavalent vaccine; (iv) implementation of communications activities to raise public awareness about the importance of a regular vaccination program; and (v) promotion of training and technical assistance for participants in the EPI, including insurers.
- 1.28 In order to carry out these measures, the MPS drew up a strategic plan that serves as the cornerstone for this operation. The plan contains four main lines of action: (i) raising vaccination rates by intensifying vaccination outreach sessions and strengthening the regular program; (ii) ensuring prompt shipment of biologicals to the departments and strengthening the cold chain in order to safeguard their quality; (iii) expanding upon information, education, and communication strategies in order to motivate administrators, suppliers, and users to be vaccinated; and (iv) continuing to take steps to strengthen public health surveillance protocols for diseases covered by the EPI and taking rapid action in response to outbreaks.

### **D. The Bank's sector strategy**

#### **1. The Bank's country strategy with Colombia**

- 1.29 The Bank's country strategy with Colombia (document GN-2267-1) sets out three basic areas in which it defines Bank actions for 2003-2006: (i) laying the foundations for economic revival and jumpstarting growth; (ii) fostering social development and ensuring that the most vulnerable groups are protected; and (iii) improving governance and supporting the reform of the State. In addition, the

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<sup>18</sup> Because vaccinations entail costs and risks for the individuals involved and because the benefits of vaccination diminish as the vaccination rate in the target population group increases, the optimum vaccination coverage rate is less than 100%. See Brito, D.L., E. Sheshinski and M.D. Intriligator, "Externalities and Compulsory Vaccinations", *Journal of Public Economics*, 1991; 45: 69-90.

country strategy identifies two major constraints: the trend in fiscal shortfalls and the escalation of the armed conflict.

- 1.30 In terms of the basic aspects of the Bank's country strategy with Colombia, the operation will primarily contribute to the achievement of objective (ii). It will do so first by increasing vaccination coverage levels, since this protective measure will help ensure children's future health. Second, improvements in the distribution and preservation of biologicals will help to provide social services that will be more effective in meeting the population's needs and more efficient in terms of resource use. Third, diminishing regional inequalities in coverage will help to reduce inequity. Protecting investment in human capital by providing broader vaccination coverage will boost the economy's potential growth rate, thereby supporting efforts to achieve objective (i). In addition, strengthening the MPS, INS, subnational health bureaus, the EPSs, and the ARSs will promote efficient State management, thereby supporting efforts to achieve objective (iii). The risks identified in the Bank's country strategy also apply to the proposed operation. The constraints associated with the size of the fiscal deficit required to attain a stable macroeconomic environment have led to budget cuts which, in the absence of sector loans to cover its expenses, could have jeopardized the EPI's allocations and execution. This constraint is still an important factor, and it is hoped that this loan instrument will help the government to safeguard vaccination expenditure levels. Another consideration is that, in the past, the armed conflict within the country has prevented some municipios from gaining access to the EPI. Since 2003, however, the EPI has succeeded in entering conflict zones thanks to arrangements made with the International Committee of the Red Cross (ICRC). The ICRC's role has been to obtain safe-conducts from the combatants in the region concerned so that the health care teams can go in.

## **2. The Bank's strategy in the social sector**

- 1.31 The document on the Bank's social development strategy (document GN-2241-1) proposes that four priority lines of action be pursued in order to help countries hasten social progress: (i) customizing health, educational, and housing reforms by gearing them to the specific needs of the population; (ii) undertaking a human development program based on a life-cycle perspective; (iii) promoting social inclusion and preventing social ills; and (iv) delivering integrated services with a territorial focus. This operation primarily addresses the second of these lines of action by making an investment in human capital formation early on in the process, defining and monitoring progress toward performance benchmarks in this area, and promoting equality of opportunity by reducing geographic and socioeconomic inequities with respect to vaccination.

### **3. The Bank's strategy for promoting timely vaccination**

- 1.32 As noted in the Bank's country strategy with Colombia, structural changes and institution strengthening in a sector take time. The Bank has a great deal of experience in the health sector, where its presence and support have given the process continuity and have made it possible to work with intermediate targets as a way of progressing toward the long-term objective. Having prepared and executed six different operations over the past 12 years, the Bank is the multilateral agency that has been the most deeply involved in the sector's reform process. The main thrust of this support effort has been to promote access to health services for lower-income groups by means of reforms and direct measures, such as: (i) registration in the subsidized contributory system; (ii) social assistance for the elderly and minors from low-income households; (iii) modification of the formulas and criteria used for revenue-sharing with subnational agencies, coupled with a clarification of the relative responsibilities of the State and the various levels of subnational institutions; (iv) regulation with a view to improving the management and financial sustainability of the subsidized scheme of the Sistema General de Seguridad Social en Salud [General Social Security Health System] (SGSSS); (v) reform of the Instituto de Seguros Sociales [Social Security Institute] (ISS) to make it efficient and financially sustainable; (vi) upgrading the efficiency and quality of health care services in public hospitals within a framework of financial sustainability over the medium term; (vii) implementation of a system for monitoring and evaluating the performance of health care service networks; and (viii) safeguarding expenditure levels for vaccination services. The experience gained in the administrative and financial management of IDB investment loans is considered to be sufficient, and the action taken has been in full compliance with Bank policies and procedures (716/OC-CO, 1525/OC-CO).
- 1.33 Safeguarding expenditure levels for vaccination programs via sector loans in 2000-2003 has directly contributed to the recovery of national vaccination rates for three key EPI vaccines following budget cuts that led to a decline in coverage in 1997-1999. This does, however, address only one aspect of the effort needed to strengthen the program's performance. First of all, there are limitations associated with the use of a projected denominator that is based on out-of-date census data (1993), particularly at the subnational level. Second, an age-appropriate vaccination rate among the nation's children has yet to be achieved. Third, conditionality provisions have applied only to national averages and have not necessarily helped to improve the level of equity with respect to vaccinations in the country's departments and municipios. Fourth, investment is needed in order to strengthen the program's cold chain and its information, education, and communication activities so that the timing of vaccinations can be improved and the demand for them can be increased. Finally, until such time as the laws are amended so as to increase the budget's flexibility, and given the current fiscal situation, measures for

safeguarding the allocation and use of funds for vaccination efforts will continue to be of key importance.<sup>19</sup>

## **E. Program strategy**

### **1. Choice of loan instrument**

- 1.34 The EPI is one of the most basic public goods provided by the State, and its benefits have been clearly established in the scientific literature. Its ultimate outcome can be easily defined, and its intermediate outputs are close approximations of that outcome. What is more, even taking into account the limitations described in Chapter I, the EPI is equipped with an information system that permits the prompt measurement of program performance using selected nationwide indicators (see paragraphs 2.5 and 2.9). At the subnational level, however, the project team chose to collect data directly by conducting a representative survey in 71 targeted municipios (see paragraph 2.6). The survey results revealed a marked variation between the rates calculated on the basis of administrative data and those based on the survey data. A significant negative correlation was also found to exist between membership in ethnic groups and vaccination rates. In accordance with the guidelines set forth in document GN-2278-2, a performance-driven loan (PDL) instrument will be used. The Bank and the country have agreed upon a timetable for performance indicators to be used during the execution period, and each tranche will be released upon achievement of the corresponding targets. If they are not reached, then the tranche will not be released.<sup>20</sup> The performance matrix is attached as Annex 1 to this document.
- 1.35 Funding will be divided into four tranches. The first tranche (20% of the loan amount) will be released once the loan contract enters into force and the conditions precedent to the first disbursement have been met. This initial disbursement will partially finance the purchase of biologicals for the coming year and the first of the investments that will need to be made in the cold chain in order to ensure the quality and prompt delivery of biologicals at the subnational level. The remaining tranches will provide reimbursement (up to the ceilings established for each component as shown in Table II-1) for expenditures made during the time between tranches in connection with biologicals, investments in the cold chain, and technical assistance, as described in the following components.

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<sup>19</sup> The fiscal situation continues to pose a number of major challenges owing to the level of the public debt. As of the end of June 2004, the central government's total debt was estimated at 53% of GDP (US\$44.651 billion). Between 2005 and 2008, Colombia will have to repay 53% of its total public debt, or around US\$5.677 billion per year.

<sup>20</sup> Although document GN-2278-2 specifies that the tranche should not be time-bound, the vaccination rate is determined on the basis of a period of one year (52 weeks).

## **2. Adaptation of lessons learned from previous operations**

- 1.36 The lessons learned from the Bank's previous experience in the health sector underscore the importance of safeguarding funding levels for the purchase of biologicals in order to maintain suitable vaccination coverage rates. In order to remedy the current financing system's shortcomings, the program will use loan resources to reimburse the cost of biologicals purchased by the EPI. As a means of ensuring the program's long-term sustainability, reimbursements to the EPI for the purchase of biologicals will be made on a declining scale during the execution period. In addition, because it will be using the PDL instrument, the government will guarantee the fiscal resources and the allocation and execution of funding on an ex ante basis for the second, third, and fourth years of the program.

## **3. The program's value added**

- 1.37 The proposed program will add significant value by: (i) working to ensure that vaccinations are given at the appropriate ages, thereby reducing the risk of exposure to disease for the children most at risk; and (ii) achieving greater equity in the distribution of vaccinations by expanding coverage in low-performance municipios, which will also lower risk levels for the poorest and most vulnerable groups within the population; and (iii) ensuring the quality and effectiveness of the vaccines and proper compliance with vaccination protocols through investments to improve the cold chain and strengthen the supervisory and management capacity of providers and oversight agencies. Use of PDLs in combination with new legal incentives at the subnational level (see paragraphs 1.19 and 4.9) and enhanced capacity to report outcomes under the EPI, will pave the way for local actions to observe protocols, monitor performance in a timely manner, and make prompt and reliable reports on the progress made in providing vaccinations. Performance monitoring using PDLs creates a virtuous circle of measurement and feedback, so that program managers can make timely decisions to enhance the impact of the intervention. The program will also contribute directly to meeting the Millennium Development Goals (MDGs) in Colombia by promoting a reduction in infant mortality and by deliberately using one of the MDG child mortality indicators—improvements in measles vaccination rates—as one of the planned indicators in the performance matrix. This rate is low, particularly in the target municipios, and an increase will be a significant step towards meeting the MDGs in Colombia.

## **F. Coordination with other donors**

- 1.38 Preparations for this program were closely coordinated with PAHO. PAHO will continue to collaborate with Colombia in order to ensure that competitive bidding for EPI biologicals and syringes will be conducted in a timely and proper manner using loan and counterpart resources. Joint planning sessions have been held, and the procurement procedures established in the program's Operating Regulations will be followed. The work has also been coordinated with the ICRC, which has

worked with the EPI to carry out vaccination campaigns in areas of the country where there are armed conflicts.

## II. THE PROGRAM

### A. Program objectives

- 2.1 The objective of the program is to increase the equity and timeliness of Colombia's EPI. Its specific objectives are: (i) to maintain each year's vaccination coverage rates for all the EPI biologicals at a suitable level for children up to age 5; (ii) to increase the coverage of an age-appropriate scheme in a target group of low-coverage municipios; and (iii) to strengthen the EPI's operational capabilities.

### B. Program description

#### 1. Program structure and expected outputs

- 2.2 The program is structured around the ultimate outcomes being sought in terms of vaccination coverage at the national and subnational levels and around intermediate outcomes under each eligible component that will permit the ultimate outcomes to be achieved. In keeping with lessons learned in similar initiatives, a small number (five) of indicators and targets that have been agreed upon with the MPS have been selected in order to ensure that priority continues to be placed on key lines of action.
- 2.3 The indicators, baseline values, and targets associated with each tranche are shown in the matrix that appears in Annex 1. Where appropriate, the targets have been set in terms of estimated ranges based on the starting point and the extrapolation of past trends in the selected indicators, adjusted to take the planned investment and its expected effects into account.
- 2.4 Each indicator is assigned a weighting based on its importance in attaining the desired outcomes and its value added. The matrix includes a total of 100 points.
- 2.5 **Outcome #1.** One of the expected outcomes at the national level is the maintenance of a useful level of nationwide coverage<sup>21</sup> for the EPI vaccines, using figures obtained from the administrative database as a numerator and, as a denominator, adjusted municipal projections prepared by the DANE on the basis of the 1993 distribution of the population between the ages of 0 and 1.<sup>22</sup> The vaccination rate is used as a program outcome because it bears a direct relationship to the rate of

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<sup>21</sup> A coverage rate of at least 85% for each biological, based on herd immunity estimates cited in the international literature (see "Herd Immunity: History, theory, and practice." *Epidemiological Review*, 1993 15:265-302).

<sup>22</sup> When the 2005 census results become available, estimates will also be computed using the corresponding denominator, though only for purposes of comparison.

deaths associated with preventable diseases covered by the EPI<sup>23</sup> and because, at the national level, the latter rate can be distorted by undercounting. Although it is an important overall EPI performance benchmark, the relative weighting of this indicator has been set at 30 because national vaccination rates are already high enough to maintain herd immunity and because there are regional differences in the quality of the data used for the numerator.<sup>24</sup>

- 2.6 **Outcome #2.** One of the expected outcomes at the subnational level is increased coverage of an age-appropriate vaccination scheme in a target group of 71 municipios (6% of the total number of municipios) with current coverage rates of below 80%. The baseline has been set with reference to a coverage survey based on the module used for the National Demographic and Health Survey of a representative sample of children under the age of 5 in the relevant municipio. Approximately 16,750 children were covered in the baseline survey. Municipios with vaccination rates below 80% in 2003 were selected for targeting<sup>25</sup> based on their poverty ranking (Quality of Life Index) and population density in order to ensure the survey's cost-efficiency. The baseline coverage survey<sup>26</sup> was conducted by an independent consulting firm specializing in coordination with EPI officials at the national and subnational levels.
- 2.7 Targets have been ranked for each target municipio, so that each municipio can work towards its specific targets, motivated by the incentives described in paragraphs 1.19 and 4.9. For purposes of the performance matrix, however, whether or not targets have been met will be determined based on the performance of the

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<sup>23</sup> According to the scientific literature on the subject, the vaccination rate is a close proxy for the morbidity/mortality rate for vaccine-preventable diseases. Although changes in this rate are not included as a condition, information on movements in the rate is to be provided in the reports accompanying disbursement requests.

<sup>24</sup> The numerator is the number of doses for each biological administered to children below the age of 1. In the course of the data quality audit of a sample of departments, municipios, and vaccination centers conducted during the preparation of this operation, inconsistencies were found between the number of pentavalent doses that were distributed and the number that were administered. Although it is difficult to determine whether this is attributable to the existence of a stock of biologicals at the local level or if it is confined to this particular vaccine, it is probable that the vaccination rate has been overestimated. Depending on the assumptions used, between 5% and 15% of the rate may correspond to overcounting. Furthermore, although there is an EPI rule to that effect, it is impossible to be sure that the number of doses that subnational agencies report to the national level as having been administered have been given to children under 1 year of age only. Once the program's information system is upgraded, this rate ought to become more accurate and may turn out to be lower. In order to provide incentives for accuracy and transparency in reporting this rate, which is of such great importance in monitoring social development, a conservative goal—i.e. maintaining a useful coverage rate—has been chosen.

<sup>25</sup> The 71 targeted municipios are located in the departments of Antioquia, Atlántico, Bolívar, Boyacá, Caldas, Cauca, Cesar, Chocó, Cundinamarca, Magdalena, Nariño, Norte de Santander, Santander, Sucre, Tolima and Valle del Cauca.

<sup>26</sup> The sample, questionnaire, and procedures for the initial application of the survey are described in detail in <http://opsws3.reg.iadb.org/idbdocswebservices/getDocument.aspx?DOCNUM=460694>.

target municipios interviewed during the follow-up surveys conducted after the baseline measurement. Fifty<sup>27</sup> of the 71 target municipios will be selected for each follow-up survey. At program end, each municipio will have received a baseline measurement and at least two follow-up measurements. The targets to be met for each tranche are those related to the average of the targets for the 50 individual municipios selected for each measurement.<sup>28</sup>

- 2.8 Owing to the significance of these indicators to the program's value added—more timely delivery of vaccinations and greater equity—and the quality of the data compiled in the representative survey of children under one year of age, the relative weighting has been set at 50.
- 2.9 **Intermediate outcomes indicators #1 and #2.** The expected intermediate outcomes are: (i) ensuring timely delivery, which will be determined by measuring the average lapse between the time that an order for biologicals is issued at the departmental level and the delivery of that order to the departmental level; and (ii) increasing the accuracy and promptness of vaccination reporting at the municipal level. The source for these indicators is the EPI database. Because these are intermediate outcomes indicators, each indicator has been assigned a relative weighting of 10.

## **2. Eligible financing**

- 2.10 Program goals will be achieved by means of three eligible loan components: (i) stabilization of the supply of biologicals and quality assurance; (ii) technical assistance for the EPI; and (iii) monitoring, follow-up, and evaluation.
- a. Stabilization of the supply of biologicals, quality assurance, and improved distribution**
- 2.11 This component's objectives are to stabilize the supply of EPI biologicals, to ensure their quality and ready availability, and to improve the distribution system. Under this component, the eligible financing covers EPI biologicals and syringes, including the purchase of the necessary biologicals and syringes to entirely eliminate rubella and congenital rubella syndrome and to pursue a flu vaccination strategy. Financing will also be provided for technical assistance in completing the municipal cold chain inventory and for investment in the necessary equipment to preserve biologicals in optimum condition. Financing for biologicals will remain fixed for years one through four of the program and will then decrease in the program's final year.

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<sup>27</sup> For reasons of cost-effectiveness, measurements are limited to 50 of the 71 target municipios.

<sup>28</sup> Therefore, the targets related to the average of all 71 municipios contained in the performance matrix are included for purposes of illustration.

### **b. Technical assistance for the EPI**

- 2.12 This component aims to strengthen the national institutions that work with the EPI (the MPS and the INS) and to help provide national-level support for EPI operations at the level of subnational agencies. This includes: (i) funding for studies, diagnostic analyses, the design of monitoring and oversight systems, publications, equipment, and inputs; (ii) funding for the design and implementation of information systems at the subnational level; (iii) training at the subnational level in relation to information systems, the cold chain, monitoring and oversight, surveillance, and other activities related to EPI operations where appropriate, including intercultural outreach methodologies; (iv) intensifying epidemiological surveillance of vaccine-preventable diseases; and (v) developing and launching public information campaigns with a view to improving access to EPI services, with special emphasis on indigenous and Afro-descendent groups.<sup>29</sup>
- 2.13 A study on the cost-effectiveness of implementing an expanded strategy for providing flu vaccinations will be an important part of the program during its first year; consideration may be given to the possibility of expanding the program to finance the procurement of additional biologicals in subsequent years. This study should not only take into account the biological for the flu, but should also include others still to be incorporated into the EPI, such as pneumococcal, rotavirus, and other relevant biologicals.

### **c. Monitoring, follow-up, and evaluation**

- 2.14 Under this component, financing will be provided for the monitoring and follow-up of the EPI's implementation pursuant to the terms of reference established for the performance audit (see Annex 2), including yearly independent performance audits based on the performance matrix. This eligible item of expenditure will be treated as a regular investment loan.

### **d. Program management**

- 2.15 This component includes the overall management of the program, as well as the costs associated with the program's annual external financial audit. This last item of expenditure will also be treated as a regular investment loan.

## **C. Cost and financing**

- 2.16 The program's total cost will be US\$133,738,415. This sum will finance the eligible expenditures summarized in Table II-1:

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<sup>29</sup> This area of activity will incorporate intercultural outreach methodologies, with emphasis on strengthening ARS services for indigenous groups.

<b>Table II-1</b> <b>Program costs</b> <b>(US\$)</b>		
<b>Investment categories</b>	<b>Total</b>	<b>% Total</b>
<b>Comp. 1: Stabilization of biologicals, syringes, and cold chain</b>	<b>127,912,088</b>	<b>95.6</b>
<b>Comp. 2: Technical assistance for the EPI</b>	<b>4,320,516</b>	<b>3.2</b>
–Technical assistance and training	980,744	0.7
–Public health laboratory	1,350,629	1.0
–Information, communications, and publications systems	1,989,143	1.5
<b>Comp. 3: Monitoring and evaluation</b>	<b>693,259</b>	<b>0.5</b>
<b>Administration, including financial audits</b>	<b>812,552</b>	<b>0.6</b>
<b>Total</b>	<b>133,738,415</b>	<b>100.0</b>
%, by source	100%	

### **III. PROGRAM EXECUTION**

#### **A. The borrower and executing agency**

- 3.1 The borrower will be the Republic of Colombia. The Ministry of Social Protection (MPS) will, through the Bureau of Public Health, be responsible for executing the various program components. The Instituto Nacional de Salud [National Health Institute] (INS) will take part in epidemiological surveillance activities and the operation of the public health laboratory.

#### **B. Program implementation and management**

- 3.2 The MPS Bureau of Public Health will bear the technical responsibility for execution of the program components. The Bureau will be supported by a technical coordination unit (TCU) composed of a general coordinator, an assistant, and a team of 14 professional staff who specialize in the subject matters required for program execution (cold chain, technical assistance, information systems, and monitoring and control). Seven of these professional staff will be located at the MPS, while the other seven will be located at the INS. The UCT will assist the Bureau with the operation and management of the EPI and will be in charge of the technical matters required to ensure program execution. The make-up and duties of the team will be specified in the program's Operating Regulations. Administrative and financial matters will be handled by the MPS office in charge of managing resources from multilateral banks.
- 3.3 More specifically, the UCT and the MPS office in charge of managing resources from multilateral banks will perform the following duties, which are specified in the program's Operating Regulations: (i) guiding, coordinating, and supervising all project activities; (ii) preparing the annual work plans (AWPs), which will include all the necessary measures for achieving the desired outcomes, in coordination with MPS and INS line units; (iii) preparing periodic technical reports; (iv) drawing up the terms of reference for specialized consulting, technical assistance, and training services provided for as eligible program expenses, in coordination with MPS and INS line units; (v) ensuring fulfillment of the AWPs as a means of achieving the desired outcomes; (vi) maintaining and strengthening existing administrative databases for use in monitoring and evaluating outputs and the program's financial and operational performance; (vii) preparing all documentation concerning fulfillment of contractual conditions, including disbursement requests; (viii) overseeing, in coordination with MPS and INS line units, the recruitment and supervision of corporate and individual suppliers of goods and services; (ix) reporting on progress toward established program targets on a regular basis; and (x) overseeing accounting and financial record-keeping related to the use of loan proceeds.

- 3.4 In view of the program's focus on improving vaccination services for indigenous and Afro-descendent groups, institutionally structured opportunities will be provided for participation by representatives of indigenous and Afro-descendent groups. This could be achieved by working with these groups' national organizations or in coordination with the Dirección de Etnias [Council on Ethnic Groups] of the Ministry of the Interior, which has its own indigenous and Afro-descendent consultative councils. These activities will be delineated in the program's first AWP.
- 3.5 The MPS has a great deal of experience in managing external assistance programs, including four IDB-funded health programs. These programs have been quite complex and, like the proposed project, have chiefly dealt with tenders for the provision of technical assistance and small-scale infrastructure. In addition, each year the MPS arranges for the receipt of bids for biologicals and inputs for strengthening the EPI cold chain through the use of the PAHO revolving fund. Support for other tenders will be provided by the Unidad Ejecutora del Programa de Apoyo a la Reforma [reform support program executing unit] and the Dirección de la Calidad de los Servicios de Salud del MPS [Quality Assurance Bureau of MPS Health Services], which houses program executing units for other external financing operations (loan 1225/OC-CO). It is therefore felt that the agencies and units involved in the program are equipped with financial management, accounting, and control systems that meet the established requirements. Detailed management guidelines for program execution are set forth in the program's Operating Regulations (see <http://opsws3.reg.iadb.org/idbdocswebsites/getDocument.aspx?DOCNUM=472281>).

### **C. Procurement of goods and services**

- 3.6 The program will finance the procurement of the biologicals, syringes, equipment, and technical assistance needed to achieve its established goals. Two different procedures will be used for the procurement of goods and services for this program.
- 3.7 The first procedure, to be used for the procurement of biologicals and syringes, will be pursued under Law 80 of 1993, which establishes the legal framework for competitive bidding processes in Colombia.<sup>30</sup> The specific bidding mechanism to be used will be the PAHO Revolving Fund for Vaccine Procurement, as described in

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<sup>30</sup> This framework's strengths include its avoidance of excessive red tape and the use of alternative means of dispute settlement. Its weaknesses include a failure to clearly define its underlying principles and proposal-evaluation methods with a view to ensuring economy and transparency in the award of contracts and the presence of various ceiling rates in each government agency for directly issued contracts. Colombia has a national procurement evaluation prepared under the provisions of Law 80 at its disposal. This evaluation, which was prepared by the World Bank and expires in late 2006, makes recommendations for the improvement of Colombia's competitive bidding and contract management systems, which are now being implemented satisfactorily by the authorities. (see <http://opsws3.reg.iadb.org/idbdocswebsites/getDocument.aspx?DOCNUM=472302>).

- 1.20 to 1.23. Executive Order 2166 of 2004 stipulates that this type of tender may be used for vaccines and syringes under the provisions of Law 80.<sup>31</sup> Colombia will negotiate a purchase contract for biologicals and syringes, with the necessary resources being drawn from the PAHO revolving fund for the duration of the program.
- 3.8 An independent, IDB-funded analysis of the system has found that this mechanism is in keeping with practices and procedures governed by the principles of competition, economy, transparency, public disclosure, equality, efficiency, and due process (see document GN-2278-2 for a definition of these principles):<sup>32</sup>
- a. *Competition.* The Fund invites all WHO-approved vaccine producers to submit bids.<sup>33</sup> This procedure is used in order to ensure that there will be sufficient competition among potential suppliers so that the program may obtain the best terms and conditions that the market has to offer.
  - b. *Economy.* The Fund has laid down very clear rules concerning all the steps to be taken in selecting suppliers and purchasing vaccines in order to save time and resources and avoid delays. The Fund also has procedures in place that ensure the swift settlement of any disputes or disagreements that may arise with regard to prequalification, selection, or performance of procurement contracts.
  - c. *Transparency and public disclosure.* When calling for bids from qualified vaccine producers, PAHO sends out copies of the Fund's selection and procurement policies. The applicable rules are therefore known to the participants and to society in general so that, should it become necessary, it can be demonstrated that they were followed to the letter.
  - d. *Equality.* The procurement procedures used by the PAHO Fund are such as to prevent any sort of preferential or discriminatory measures whatsoever that might favor or jeopardize the interests of some participants, to the benefit or detriment of others.
  - e. *Efficiency.* All Fund acquisitions are planned and programmed with a view to securing the best possible conditions in terms of scheduling, cost, and quality.
  - f. *Due process.* The representatives of bidders are invited to be present when the bids are opened in October of each year at PAHO headquarters in Washington

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<sup>31</sup> See paragraph 4.9 on the risks associated with this decision.

<sup>32</sup> The policies governing selection and procurement by the PAHO Revolving Fund for Vaccine Procurement are outlined in the document entitled, "Bid Solicitation for Vaccines 2005". (see <http://opsws3.reg.iadb.org/idbdocswebsites/getDocument.aspx?DOCNUM=460571>).

<sup>33</sup> Up-to-date lists of prequalified suppliers for each product, as well as prequalification requirements, are posted on the following webpage: [http://www.who.int/vaccines-access/quality/vaccine\\_quality\\_front.htm](http://www.who.int/vaccines-access/quality/vaccine_quality_front.htm).

D.C. so that they may be satisfied that the rules governing the selection of suppliers have been respected.<sup>34</sup> Complaints, disputes, or disagreements among the parties that cannot be settled amicably within 60 days will be resolved by arbitration in accordance with the applicable rule of the United Nations Commission on International Trade Law (UNCITRAL).

- 3.9 At the government's request, the second type of tender, to be used in calling for bids for technical assistance (consulting services) and equipment (goods), will employ the procedures specified in Bank procurement policies and processes. International competitive bidding procedures must be used for the procurement of goods valued at over US\$350,000 equivalent and for the engagement of consulting services for sums in excess of US\$200,000 equivalent when such transactions are financed either partially or wholly with loan proceeds. These limits are justified by the interest that potential national and international suppliers, contractors, and consultants have shown in the project and by prior experiences with competitive bidding rounds and the participation of foreign enterprises in them. Tenders involving sums below those thresholds will be conducted in accordance with the relevant national legislation. Because this is a PDL, a procurement plan has not been included.

#### **D. Implementation and disbursement timetable**

- 3.10 The length of time required to execute the program is estimated at four years, and the maximum disbursement period will be five years. The tentative net disbursement plan shown below provides for an initial disbursement and four subsequent tranches.

**Table III-1**  
**TENTATIVE NET DISBURSEMENT PLAN (US\$ million)**

<b>Source</b>	<b>Initial disbursement</b>	<b>Tranche I Year 1</b>	<b>Tranche II Year 2</b>	<b>Tranche III Year 3</b>	<b>Tranche IV Year 4</b>	<b>Total</b>
<b>IDB disburs.</b>	21.4	24.3	28.3	28.6	3.9	107
<b>% of IDB program</b>	20.0	23.0	26.4	26.7	3.6	100.0

The sum of the entries does not coincide exactly with the total due to rounding.

- 3.11 The initial disbursement, of up to 20% of the loan, will be made once the loan contract has entered into force and the conditions precedent to the first disbursement have been met. This initial disbursement will partially finance the purchase of biologicals for the coming year and the first of the investments that will

<sup>34</sup> The criteria used in selecting suppliers are: (i) price; and (ii) past record with regard to prompt delivery.

need to be made in the cold chain in order to ensure the quality and prompt delivery of biologicals at the subnational level.

- 3.12 As stated in document GN-2278-2, by which PDL operations were approved as a pilot program, this initial payment is to be deducted from the first disbursement. The borrower has requested, as an **exception to this policy**, that, in this specific case, the deductions of the initial payment be spread out over the tranches of the performance-driven loan on a proportional basis. The reason for this request is that this would provide a way of ensuring the availability of the cash flow needed to purchase biologicals and syringes at the start of each year. Colombia is faced with major fiscal constraints and, as a result, liquidity levels are low at the start of each fiscal year. If the initial payment has to be deducted in its entirety from the first disbursement, the MPS' ability to produce the outcomes that are to be achieved in the program's second year will be seriously jeopardized. The proposed exception, on the other hand, by making it possible to deduct the initial payment from the subsequent tranches on a proportional basis, would stabilize the cash flow at the start of each year and thus permit the vaccines to be purchased and distributed on time.
- 3.13 The amount of Bank financing will remain fixed for the first three years of the program, with a substantial increase in the government's contribution in the final year in order to ensure the sustainability of the EPI once the program concludes. Each tranche will be released once the targets defined in the performance matrix have been met and a favorable performance audit has been issued. Generally speaking, it is expected that the tranches will be released in March of each calendar year, provided that the necessary statistics are available to allow the calculation of the relevant indicators.
- 3.14 The supporting information for the release of all the PDL tranches will be reviewed on an ex post basis. As noted in paragraph 3.5, the financial management, accounting, and internal control systems of the MPS are sound enough to permit the use of this modality for the review of the relevant documentation.

## **E. Monitoring and evaluation**

### **1. Monitoring**

- 3.15 The Country Office in Colombia will play an active role in the Bank's monitoring of the program based on established inspection and supervisory procedures to ensure its satisfactory execution, with due consideration for the special attributes of a PDL. The borrower is expected to cooperate with the Bank by providing any necessary assistance and information. Support is also to be provided for annual administrative missions.

- 3.16 The executing agency will submit semiannual reports on program execution to the Bank in May and November of each calendar year. These reports will cover the progress made in achieving program outcomes, using the program's administrative database, and will measure that progress against the intermediate and final indicators identified in the performance matrix (Annex 1). These reports are also to include information on the expenditures made in eligible categories. In both cases, the reports should, in addition, cover any measures taken by the executing agency to remedy delays in the original timetable for outcomes and eligible expenditures.
- 3.17 The Bank will use this information to prepare periodic updates of the Project Performance Monitoring Report (PPMR). In the particular case of this PDL, the PPMR will be modified to emphasize the monitoring of program outcomes and to provide information on the steps taken by the executing agency in the event of significant delays in progress toward the targets agreed upon for each tranche. Importance will also be placed on the external auditors' findings regarding financial and operational matters during program execution.
- 3.18 In addition, the Bank will conduct regular annual reviews, a midterm evaluation, and a final evaluation. The main inputs for these assessments will be program outcomes, measured against the intermediate and final indicators as set forth in the program performance matrix for each stage. Supporting information will be provided by the executing agency's semiannual reports and the PPMR.
- 3.19 In accordance with existing policies and procedures, Colombian authorities were consulted regarding their willingness to carry out an ex post program evaluation. The authorities indicated that they would prefer not to conduct such an evaluation. They did, however, agree to keep the necessary records on outcomes indicators and to make that information available to the Bank so that an ex post evaluation may be prepared at a later date if it is deemed necessary to compile empirical evidence on the program's impact in increasing vaccination and reducing vaccine-preventable mortality and morbidity. With due consideration to the special attributes of a PDL, the findings and results of an ex post evaluation would make it possible to ascertain what happens, in terms of program outcomes, after such a project has been completed. This would also make it possible to project future improvements or setbacks, along with the possible technical reasons for them, and to identify mechanisms for enhancing the sustainability of the targets and outcomes that have been achieved.

## **2. Performance audits**

- 3.20 To ensure independent verification of the outcomes associated with each disbursement (other than the initial payment), the achievement of the corresponding targets will be reviewed by means of a performance audit. This audit will examine and evaluate the quality of the data generated by the performance monitoring systems by analyzing their accuracy, reliability, relevance, and credibility.

**a. Disbursement requests**

- 3.21 When the government wishes to request a disbursement, it will submit an official report on the progress made toward the targets established in the performance matrix and will request that an independent performance audit be conducted. This official report will contain: (i) a general progress report on the EPI; (ii) a table, prepared based on administrative data, that shows the extent to which the targets defined in the performance matrix have been met (in the case of the target municipios, only the vaccination rate for the target groups will be reported); (iii) a description of trends in the relevant indicators during the period between one tranche and the next; (iv) a report on the status of vaccine-preventable diseases during the same period; (v) a progress report on the introduction of policies and regulations concerning safe syringe disposal; (vi) a progress report for the indicator on vaccine spoilage resulting from breaks in the cold chain and/or management error; and (vii) a progress report on the introduction of public information campaigns to promote vaccination. The Bank will make the government's report available to the organization that is to conduct the performance audit.

**b. Evaluation methodology**

- 3.22 The audit will be conducted using the methodology specified in the terms of reference (see Annex 2). The audit will: (i) ascertain the quality and degree of reliability of the administrative data furnished by the government in its disbursement request; (ii) determine the extent to which the targets have been met (In the case of outcome indicators #2 and #3, the auditing firm will conduct a follow-up survey in 50 of the 71 target municipios (selected at random each year using the baseline methodology) so that each target municipio can be monitored at least once); and (iii) make a recommendation to the Bank regarding disbursement.
- 3.23 In order to determine eligibility for a disbursement, the auditing firm will take the relative weightings<sup>35</sup> assigned to each indicator and its corresponding target into consideration (see Annex 1) and will calculate an overall program performance score. This strategy for evaluating performance in relation to the overall matrix is based on the international literature regarding public-sector performance contracts,<sup>36</sup> which recommends the use of weightings for priority-setting purposes. It also recommends that a scoring range be used for performance matrices as a whole so that overall program performance can be ranked. This also provides a suitable way of handling the statistical uncertainty associated with any target-setting exercise; it also makes it possible to establish more ambitious targets while taking into account the inevitable limitations of administrative databases.

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<sup>35</sup> These weightings may not be modified during program execution.

<sup>36</sup> See Kamioka, N., "Bibliografía anotada sobre la medición del desempeño y el uso de contratos" [Annotated bibliography on measuring performance and the use of contracts], IDB, INDES, July 1998.

3.24 In order to determine whether or not targets have been met, a scale of program performance scores and their accompanying ratings, ranging from excellent to unsatisfactory (see the table below), has been established for disbursement purposes. If the program's progress is rated as unsatisfactory, with a score below 80 out of a total of 100, then no funds will be disbursed. If rated as "satisfactory", then 100% of the requested amount will be disbursed because this level of performance will mean that both the program objectives and the overall target have been met.

<b>Evaluation table</b>	
Excellent	100-90
Satisfactory	80-89
Unsatisfactory	<80

3.25 Incentives for reaching the level of "excellent" rather than "satisfactory" are related to the concentration of the matrix's weightings in achieving the indicators in the target municipios, where there is a system of monetary incentives under Law 715 for municipios to meet the established targets.

**c. Auditor selection and audit time frame**

3.26 The time frame for the audit can be broken down into two phases: one phase corresponds to the audit of administrative data at the national level, which is to be carried out within a period of no more than three weeks following the government's submission of a disbursement request; the second refers to the gathering of information from the target municipios and is to be conducted in September and October of each calendar year. The purpose of this exercise is to ensure baseline comparability and to provide inputs for the government's disbursement request.

3.27 An international competitive bidding process, in keeping with Bank procedures, will be held in order to select a private consulting firm, university, or other independent organization to conduct the independent performance audit. The Bank will engage this organization directly and will use loan funds for this purpose. The terms of reference for this performance audit will be an integral part of the loan contract.

3.28 Due to the special nature of the program, audits will be supervised by the Bank's Country Office in Colombia with ongoing technical assistance from the Social Programs Division 3 at Bank headquarters. For such purpose, an annual loan administration mission will be scheduled to coincide with the release of the audit report and the disbursement request.

### **3. External financial audit**

- 3.29 The external audit of organizations involved in program execution will be conducted by a firm of independent auditors acceptable to the Bank pursuant to Bank policies and procedures for such contracts (AF-200). The purpose of this external financial and operational audit will be to ensure that program resources have been used to defray eligible expenses that are necessary to produce the desired outcomes. To this end, provision is made for an ex post review of all supporting documentation for the release of each tranche. The cost of this audit is included in the program as an eligible administrative expenditure.
- 3.30 The executing agency will submit annual financial statements, audited by the external auditing firm, to the Bank in accordance with terms of reference previously approved by the Bank (AF-400). Within 60 days after each disbursement request, it will also submit a report on the ex post review of procurement procedures followed under this modality, together with all the supporting documentation used to substantiate that request, in accordance with terms of reference previously approved by the Bank (AF-500).

## IV. FEASIBILITY AND RISKS

### A. Institutional feasibility

- 4.1 The EPI is considered to have functioned fairly well at the national level in recent years in the areas of policy-making, on-time delivery of biologicals for use in the program, program advocacy, dissemination of information, and development of strategies for performing its duties at the various levels (e.g. vaccination campaigns). Its main weaknesses have to do with the limited nature of the technical assistance provided by the national program at the subnational level and an insufficient level of supervision and oversight by the national government.<sup>37</sup> In addition, because the denominators for vaccination rates are derived from such an old census, the quality of vaccination data at the subnational level—the principal indicator for the EPI’s management and performance—poses a problem. Measurements taken of the baseline in the 71 target municipios indicate that the error goes in both directions, with rural municipios exhibiting a significant underestimation of vaccination rates and more urban municipios displaying just the opposite.
- 4.2 This operation will build on the EPI’s institutional strengths while taking the necessary steps to improve operations at the subnational level. It will also work to ensure a suitable, timely flow of information among the different levels of government in order to enable the national government to supervise the program more effectively. Independent measurements of vaccination rates taken in low-coverage municipios as part of the annual performance audit will also provide reliable data for use in evaluating the program in selected municipios.

### B. Financial feasibility

- 4.3 EPI expenditures have amounted to approximately US\$30 million per year. Based on the upward trend in the cost of biologicals observed between 2001 and 2004, this sum is projected to increase—even without considering the possible addition of a new vaccine to the program—by about 4% each year. The additional expenses associated with the proposed program—investments in the cold chain, the purchase of flu vaccines, and institution-strengthening—are marginal. In 2005, the EPI will

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<sup>37</sup> EPI supervision is a responsibility shared by the national-level EPI and the Office of the Superintendent for Health Services. In recent years the Office of the Superintendent has not played a proactive role because it lacks sufficient operational capacity to mount timely responses at all levels of government. Additional factors include changes in superintendents, structural reorganizations, and the existence of such a wide range of functions that the Office of the Superintendent has been unable to consolidate an inspection, oversight, and control system or to properly monitor the technical, scientific, administrative, and financial aspects of public health in general.

represent 1% of the total national investment budget;<sup>38</sup> this is a relatively minor sum, and the financial burden it represents is a fully sustainable one for the country.

### **C. Environmental and social impact**

4.4 **SEQ/PTI classification.** The program will increase vaccination coverage levels and make the vaccination rate more equitable, with emphasis on the poorest and most marginal municipios; these municipios are also where the Afro-descendent and indigenous population is concentrated. It will also use new ways of reaching out to these communities in order to increase their members' knowledge about health issues and vaccination coverage. This operation automatically qualifies as a poverty-targeted investment (PTI) because the loan proceeds will be used to support a primary health care program. The country has opted to use the additional ten percentage points of financing.

4.5 **Environmental strategy.** Improper disposal of used syringes is a potentially adverse environmental impact of the program. The program is mitigating this risk, however, by running an efficient safe-disposal project, which has now been operating in all the municipios of Colombia for a decade. The recommended procedure for the disposal of used syringes is incineration, outdoor combustion, and burial. The forms of disposal used in the EPI are safety boxes and narrow-necked plastic bottles. The regulations do not permit the re-use of syringes. The EPI does not routinely keep records on enforcement of the regulations. In order to address this situation, the new information system to be financed by the program will include an indicator for waste disposal. This indicator will be used to monitor existing practices and will serve as a basis for corrective measures in accordance with national regulations, where appropriate. The indicator will not be incorporated into the performance matrix because no baseline is available, but it will be included in the government's disbursement request reports.

4.6 **Social strategy.** The EPI is holding consultations with the ARSs serving indigenous groups in order to determine what the most effective communication and intervention strategies would be for improving the distribution and storage of biologicals for areas populated by indigenous groups. These recommendations will be incorporated into the EPI's Operating Regulations and will be applied during program execution. Progress reports will also be provided on the headway being made in improving vaccination rates among the various ethnic groups in the target municipios.

### **D. Benefits and beneficiaries**

4.7 Childhood is a crucial stage in determining a person's future health. Vaccination is one of the most economical and effective measures for ensuring that children will

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<sup>38</sup> Not including wages, pensions, or expenditures at the subnational level.

be healthy later on. Preventive vaccines are the only available means of averting a number of serious or even fatal diseases. Apart from protecting people's health during childhood, vaccination can also prevent certain chronic diseases from appearing during adulthood. There are a number of studies that demonstrate a connection between contagious/infectious diseases during childhood and chronic illnesses during old age. For example, if a child catches tuberculosis or hepatitis B, s/he will be more likely to develop diabetes or chronic heart or lung disease as an adult. The benefits of vaccination are not limited to the individual either; it provides benefits for the entire community by preventing the spread and rapid contagion of certain infectious diseases. In addition to its impact on the population's health, vaccination can forestall the productivity losses associated with morbidity and mortality and thus permit other types of human capital formation, such as those associated with educational achievement, etc.

## **E. Risks**

4.8 **EPI fiscal priority and sustainability.** Given the effort to hold down the fiscal deficit and the highly inflexible nature of the national budget, support for previous sector programs has been an important factor in permitting the country to assign an increasing priority to EPI allocations and expenditures. In the absence of budgetary reforms, in order to uphold the priority assigned to the program, this operation will maintain a specific allocation for EPI execution. The government is expecting passage of a budget reform bill that will make the budget more flexible in 2005, thereby permitting it to make the EPI a definitive priority for the future. In addition, the use of the PDL instrument will pave the way for the ex ante creation of opportunities to secure the fiscal resources needed to achieve the desired program outcomes.

4.9 **Decentralization.** The effort to decentralize health services in Colombia began with Law 10 of 1990, was furthered by the 1991 Constitution, and was brought to fruition with the passage of Law 60 of 1993 (Decentralization of Resources and Functions Act). Law 60 and a subsequent law (Law 715 of 2001) assign the job of financing and ensuring the delivery of second- and third-tier health services to the country's departments, while first-tier health services (including vaccination) fall within the jurisdiction of the municipios. The management and regulation of health services at the national level are assigned to the Ministry of Health (now the MPS) and the National Social Security Council (Law 100 of 1993). At present, the municipios are responsible for providing vaccinations, and the law requires them to use the transfers they receive under the revenue-sharing scheme for this purpose. Given the very limited degree of financial leverage that exists between the central government and the municipios, however, some municipios have used the resources they have received for vaccination programs for other municipal priorities, in violation of the law. In order to mitigate this risk, funding will be provided for closer supervision in these municipios and for social oversight and communication tools with a view to making the mayors of these municipios more accountable to

their constituencies. In addition, under Law 715, a system of performance bonuses at the municipal level has been created which should provide an incentive for the appropriate use of PAB resources. The Bank is funding an assessment of Law 715 as part of another operation (1382/OC-CO), and the resulting findings and recommendations that refer to vaccination will be taken into account during program execution.

- 4.10 **Legal feasibility of purchasing vaccines via the PAHO revolving fund.** A finding issued by the Constitutional Court (C-249/04) concerning Paragraph 4 of Article 13 of Law 80 of 1993 (“Paragraph 4”) and a directive on the same subject issued by the Attorney General (Directive No. 10 of 21 May 2004) could be interpreted as posing an obstacle to the use of the PAHO revolving fund. There is also a bill currently before Congress to amend Law 80 in ways that might have a similar effect. However, at the request of the MPS, the Attorney General has issued a report (dated 8 June 2004) expressing the view that "within the framework of the execution of an instrument of international cooperation ... having the purpose of acquiring specific goods for the achievement of express objectives of cooperation and technical assistance, it is possible to apply the special contracting regime established by international bodies [which is] applicable in the context of [Paragraph 4]”. Taking into account both the Attorney General’s report and the favorable position adopted by the National Planning Department (Decree No. 2166 of 2004) on the legal matter at issue, as well as the uncertainty surrounding the question as to whether or not the aforementioned bill will be passed, it is felt that, although the issue of the legal feasibility of using the revolving fund continues to be a risk for the program, it is a sufficiently mitigated one. In addition, the loan contract will make explicit reference to the contracting of PAHO as a condition for the Bank’s loan; this will also strengthen the legal character of the plan to contract PAHO as an element of international cooperation permitted under the terms of Paragraph 4.

**STRENGTHENING THE EXPANDED PROGRAM ON IMMUNIZATION (EPI) 2005-2008  
(CO-L1002)**

**PERFORMANCE MATRIX**

<b>Objectives</b>	<b>Outcome indicators</b>	<b>Relative weightings</b>	<b>Initial disbursement: Baseline (2004)</b>	<b>Target – first tranche<sup>1</sup></b>	<b>Target – second tranche</b>	<b>Target – third tranche</b>	<b>Target – fourth tranche</b>
<p><b>Objective #1: National coverage</b> Maintenance of the nationwide level of useful coverage for each EPI biological<sup>2</sup></p>	<p><b>Outcome indicator #1 – National level:</b> For example: (# of children under one year of age who have received the third dose of polio vaccine / total # of children under one year of age) * 100</p>	0.30	<p>OPV: 90% DPT/penta: 90% BCG: 94% Hep B: 90% HiB: 91% (denominator = 909,006 children under one year) T.V.: 92%<sup>3</sup></p>	At least maintain above 85%	At least maintain above 85%	At least maintain above 85%	At least maintain above 85%
<p><b>Objective #2: Municipal coverage</b> Expanded coverage of complete vaccination series for children under five years of age in a target group of 71 municipios with current coverage levels of below 80% (using a coverage survey conducted among a</p>	<p><b>Outcome indicator #2a – Universe of target municipios:</b> (# of children under one year of age in a defined sample who have received an age-appropriate series of vaccinations (national EPI protocol) / total # of children under one year of age in a defined sample) * 100</p>	0.35	<p>71% (see attached files<sup>4</sup> for municipal targets)<sup>5</sup></p>	72-76%	75-78%	77-80%	78-85%

<sup>1</sup> For the 52 weeks preceding the date of the request, the same scheme is to be used for each tranche. A period of at least 52 weeks will be maintained between tranches owing to the nature of the indicator.

<sup>2</sup> The methodology for calculating this denominator is described at: <http://ops3.reg.iadb.org/idbdocswebservice/getDocument.aspx?DOCNUM=472584>. When the 2005 census results become available, an estimate will be prepared using that denominator as well. The denominators for 2005-2008 can be found at <http://ops3.reg.iadb.org/idbdocswebservice/getDocument.aspx?DOCNUM=515478>.

<sup>3</sup> Denominator: 895,634 children aged 12 – 23 months.

<sup>4</sup> <http://ops3.reg.iadb.org/idbdocswebservice/getDocument.aspx?DOCNUM=460688>.

<sup>5</sup> The targets to be met for each tranche are those related to the average of the targets for the nearly 50 individual municipios selected at random for each measurement taken. Therefore, the targets related to the average of all 71 municipios in this performance matrix are included for purposes of illustration.

Objectives	Outcome indicators	Relative weightings	Initial disbursement: Baseline (2004)	Target – first tranche <sup>1</sup>	Target – second tranche	Target – third tranche	Target – fourth tranche
representative sample of children under five years of age from the municipio or location in question).	<b>Outcome indicator #2b – Universe of target municipios:</b> (# de children between 12 and 23 months of age in a defined sample who have received the three-in-one viral / total # of children between 12 and 23 months of age in a defined sample) * 100	0.15	69%	71-74%	73-77%	75-79%	77-84%

Intermediate objectives	Intermediate outcome indicators	Relative weightings	Initial disbursement: Baseline (2004)	Target – first tranche	Target – second tranche	Target – third tranche	Target – fourth tranche
<b><u>Intermediate objective #1: Quality and prompt delivery of biologicals:</u></b> The quality and prompt delivery of biologicals are ensured by expanding the cold chain.	<b><u>Intermediate outcome indicator #1 - Prompt delivery:</u></b> <sup>6</sup> For departments with > 5 days average time between the order and delivery of each type of biological at the national level.	0.10	6.9 days, on average, in 17 departments <sup>7</sup>	6.5 – 6 days	5.9 – 5.5 days	5.4 – 4 days	4 days
<b><u>Intermediate objective #2: Accuracy and prompt reporting in the EPI information system:</u></b> EPI reporting from the municipal to the central level is accurate and prompt.	<b><u>Intermediate outcome indicator #3 – National level:</u></b> (# of departments and districts submitting coverage reports for 90% or more of their municipios within four weeks after the end of the month in question / total # of departments and municipios (36) that should report).	0.10	85%	87-90%	89-92%	91-95%	> 94%

<sup>6</sup> The baseline and target for each department can be found at: <http://ops3.reg.iadb.org/idbdocsweb/services/getDocument.aspx?DOCNUM=480045>.

<sup>7</sup> These departments had data available during the preparation phase. In subsequent years, information will be provided on all 32 departments.

**TERMS OF REFERENCE**  
**PERFORMANCE AUDIT: STRENGTHENING THE EXPANDED PROGRAM**  
**ON IMMUNIZATION (EPI) 2005-2008**  
**(CO-L1002)**

**I. BACKGROUND**

The Program for Strengthening the Expanded Program on Immunization (EPI) 2005-2008 (CO-L1002) is a performance-driven loan, which will set annual targets for a series of performance indicators. To ensure an independent verification of the outcomes associated with each disbursement, achievement of those targets (except in the case of the initial payment) will be reviewed by means of a performance audit. This audit will examine and evaluate the quality of the data generated by program monitoring systems based on an analysis of the accuracy, reliability, relevance, validity, and credibility of the data in question. A specified range of acceptable performance is identified for each annual target and a weighting is assigned to each one, with the overall matrix totaling 100. An evaluation table is used to determine the program's overall performance and to establish clear-cut criteria for disbursements.

When the government wishes to request a disbursement, it will submit an official report on the progress made toward the targets established in the performance matrix and will request that an independent performance audit be conducted. This official report will contain: (i) a general progress report on the EPI; (ii) a table, prepared on the basis of administrative data, that shows the extent to which the indicators defined in the performance matrix have been achieved (in the case of the targeted municipios, only the number of doses administered to the target population will be reported); (iii) a description of trends in the relevant indicators during the period between one tranche and the next; (iv) a report on the status of vaccine-preventable diseases during the same period; and (v) a progress report on the introduction of policies and regulations concerning safe syringe disposal. The Bank will make the government's report available to the organization that is to conduct the performance audit.

**II. OBJECTIVE**

The objective of these consulting services is to carry out four performance audits that will then be officially reported by the Government of Colombia pursuant to the conditions set forth in the performance matrix of the Program for Strengthening the Expanded Program on Immunization (EPI) 2005-2008 (CO-L1002).

**III. ACTIVITIES**

The audit will include the following activities:

**Determine the quality and degree of reliability of the administrative data reported by the government in its disbursement request.** The purpose of this activity is to serve as point of reference for an analysis of the administrative statistics contained in the report and their possible adjustment on the basis of those findings. The auditing firm will review the results reported for outcome indicator #1 (OI#1) and intermediate outcome indicators #1-3 (IOI#1, IOI#2, IOI#3) and will audit a sampling of the administrative reports serving as a basis for the reported figures.

For OI#1, four departments will be chosen at random; 8 municipios and 16 vaccination centers in those departments will then be selected, also at random. The degree of consistency (expressed as a percentage of the number of administered doses that are verified at each level) between the administrative reports at each level will then be determined. The Data Quality Audit Colombia (DQAC) report (Lopes, et al., 2005) will be used as a methodological reference. The degree of consistency required for a positive finding will be, at a minimum, greater than the degree of consistency found in the DQAC report.

For the intermediate outcome indicators, the reported figure(s) will be verified by examining a random sample of the administrative reports on which the disbursement request report is based. The consulting firm will establish a standard methodology for determining the reports' degree of reliability.

In each case, the limitations encountered in terms of random selection will be documented (e.g. in the event that a municipio has to be ruled out for reasons of public order), as will the actual feasibility of generalizing on the basis of the findings. The auditor's report will also formulate hypotheses as to the reasons for any inconsistencies that are detected and will make recommendations as to how the EPI can correct the shortcomings it identifies.

**Determine the degree to which the targets have been met.** In the case of outcome indicators #2 and #3, the auditing firm will conduct a follow-up survey in 50 of the 71 target municipios each year using the methodology established in the baseline and described in the following electronic link:  
(<http://opsws3.reg.iadb.org/idbdocswebservices/getDocument.aspx?DOCNUM=479892>).

**Recommendation to the Bank concerning disbursements.** In order to arrive at this decision, the auditor will consider the relative weightings assigned to each indicator and corresponding target in the performance matrix and will calculate an overall performance score for the program based on the relative scores and the evaluation table shown below.<sup>1</sup> Disbursement will be recommended if the resulting score is 80 points or more.

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<sup>1</sup> The number of units refers to the "second-tier indicators" included under each indicator. For example, in the case of OI#1, the vaccination rate for each biological is measured at the national level, thereby giving rise to 6 second-tier indicators.

Table 1:

	Max. score	# Units	Relative weighting
OI 1	30	6	5
OI 2.a	35	1	35
OI 2.b	15	1	15
IOI 1	20	32	0.6
IOI 2	10	1	10.0
Total	100		

Evaluation table

Excellent	100-90
Satisfactory	80-89
Unsatisfactory	< 80

**Time frame for the audit.** The timetable for the audit is divided into two phases: one phase corresponds to the audit of administrative data at the national level, which is to be carried out within a period of no more than three weeks following the government's submission of a disbursement request; the second refers to the task of gathering information from the 71 target municipios and is to be conducted in September and October of each calendar year. The purpose of this exercise is to ensure the comparability of the baseline and to provide inputs for the government's disbursement request.

#### IV. EXPECTED OUTPUTS

Four reports having the aforementioned characteristics will be produced.

#### V. CONSULTING SERVICES

An international competitive bidding process, in keeping with Bank procedures, will be held in order to select a private consortium or firm, a university, or another independent organization to conduct the independent performance audit. The Bank will engage this organization's services directly and will use loan funds for this purpose.

The loan proposal will be made available to all participants in the bidding process.

The selected agency or consortium of agencies must have: (i) a proven ability (at least three surveys using samples of more than 1,000 households) to conduct household surveys in rural areas of Colombia; and (ii) a proven ability to analyze administrative databases in the health field (at least 10 years of experience). Preference will be given to groups that have conducted health impact assessments in Colombia in the past.